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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/810,755	03/26/2004	Michael J. Renzi	PRD2052USNP	9072

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EXAMINER	
DEBERRY, REGINA M	

ART UNIT	PAPER NUMBER
1647	

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10/11/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/810,755	RENZI ET AL.	
	Examiner	Art Unit	
	Regina M. DeBerry	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 August 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *14-16,18-21,23,24,59 and 60* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *14-16,18-21,23,24,59 and 60* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *5/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Status of Application, Amendments and/or Claims

The amendment filed 06 August 2007 has been entered in full. Claims 1-13, 17, 22, 25-58 were canceled. New claims 59 and 60 were added. Claims 14-16, 18-21, 23, 24, 59 and 60 are pending and under examination.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on 14 May 2007 has been considered by the Examiner. However, because Application No. 09/547,220 cited therein is not a true publication with a publication date, it is not fully in compliance with 37 CFR 1.97 and thus it will not be printed on the face of the patent issuing from this application.

Withdrawn Objections And/Or Rejections

The rejection to claims 1-13 under 35 U.S.C. 112, second paragraph, as set forth at pages 2-3 of the previous Office Action (08 May 2007), is *withdrawn* in view of the amendment (06 August 2007).

The rejection to claims 1-6, 10, 13-19, 23 under 35 U.S.C. 102(a) as being anticipated by Ehrenreich et al. (reference submitted by Applicant, Molecular Medicine 8(8):495-505, 2002), as set forth at pages 3-4 of the previous Office Action (08 May 2007), is *withdrawn* in view of the amendment (06 August 2007).

The rejection to claim 18 under 35 U.S.C. 102(b) as being anticipated by Ehrenreich (reference submitted by Applicant, CA 2 353 553 A1), as set forth at page 4 of the previous Office Action (08 May 2007), is *withdrawn* in view of the amendment (06 August 2007).

The rejection to claims 9, 11, 12, 22 and 24 under 35 U.S.C. 103(a) as being unpatentable over Ehrenreich, (CA 2 353 553 A1) as applied to claims 1 and 14, and further in view of Alafaci et al. (reference submitted by Applicant, European Journal of Pharmacology, 406:219-225, 2000) and Brines et al. (reference submitted by Applicant, PNAS, Vol. 97, No. 19, pages 10526-10531, September 12, 2000) as set forth at pages 4-6 of the previous Office Action (08 May 2007), is *withdrawn* in view of the amendment (06 August 2007).

Matter of Record

Please note that the rejection to claim 18 under 35 U.S.C. 102(b) as being anticipated by Ehrenreich (CA 2 353 553 A1), was withdrawn because of the limitations in the newly amended claims. This rejection will be reapplied to the instant claim if the claim language is amended. Please see the 35 U.S.C. 112, first paragraph, written description, new matter rejection below.

Claim Rejections - 35 USC § 102(b)

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 14-16, 19, 20, 21, 23, 24, (and new claims 59 and 60) remain rejected under 35 U.S.C. 102(b) as being anticipated by Ehrenreich (reference submitted by Applicant, CA 2 353 553 A1). The basis for this rejection is set forth at page 4 of the previous Office Action (08 May 2007).

Applicant's arguments did not address the instant rejection. The rejection is still maintained.

Ehrenreich et al. teach that EPO is applied as a drug advantageously with a dosage at an amount of 5,000 to 100,000 units (page 4, 4th paragraph and claims)(i.e. each dose of EPO being about 2500 IU/kg to about 10,000 IU/kg). Ehrenreich et al. teach the intravenous infusion of rhEPO starting within 8 hr of initial stroke symptoms, then again at approximately 24 hours and again at approximately 48 hours after the stroke (bottom of page 5-top of page 6 and top of page 7). Thus, EPO infusion 24 hours after the stroke would be 16 hours after the first dose (i.e. second dose of EPO delivered w/i about 8 to about 26 hrs after the first dose) and EPO infusion 48 hours after the stroke would be 24 hours after the second dose (i.e. third dose of EPO delivered w/i about 8 to about 24 hours after the second dose). Ehrenreich et al. teach that the EPO serum concentration achieves its maximum within the first few days then decreases sharply subsequently (i.e. long-acting EPO). The scientific reasoning and evidence as a whole indicates that the rejection should be maintained.

NEW CLAIM REJECTIONS/OBJECTIONS

Claim Rejections-35 USC § 112, First Paragraph, Written Description (New Matter)

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 14-16, 18-21, 23, 24, 59 and 60 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **This is a new matter rejection.**

The specification as originally filed does not provide support for the invention as now claimed:

"each dose of EPO being about **2500 IU/kg to about 10,000 IU/kg**" (claim 14)

"wherein the third dose of EPO is delivered **at about 60 hours after the ischemic event**" (claim 18)

"wherein each EPO dosage delivered is from about **5000 IU/kg to about 10,000 IU/kg**" (claims 20 and 24)

"wherein each EPO dosage delivered is **about 10,000 IU/kg**" (claim 21).

Applicant's amendment, filed 06 August 2007, asserts that no new matter has been added, but does not provide sufficient direction for the written description for the above-mentioned "limitations".

The Examiner has located in the specification, "Further, **a third dose of EPO can be delivered within about 20 hours to about 60 hours after the ischemic event**" (page 3, lines 1-3). The Examiner has located in the instant specification, "Preferred embodiments of this invention also include dosing regimens and methods of treatment wherein each **EPO dosage delivered is selected from about 500 IU/kg to about 10,000 IU/kg**.." (page 3, lines 8-10). The Examiner has located in the instant specification, "In another embodiment, each **EPO dosage delivered is selected from about 2500 IU/kg to about 5000 IU/kg**" (page 3, lines 15-17).

The specification as filed does not provide a written description or set forth the metes and bounds of the "limitations" in the instant claims. The newly amended claims **changes the range of EPO dosages and times of EPO administration**. These new range limitations were not contemplated at the time of filing and result in new matter. The instant claims now recite limitations, which were not clearly disclosed in the specification as originally filed, and now change the scope of the instant disclosure as-filed.

Applicant is required to cancel the new matter in the response to this Office action. Alternatively, Applicant is invited to provide specific written support for the "limitations" indicated above or rely upon the limitations set forth in the specification as filed.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Regina M. DeBerry whose telephone number is (571) 272-0882. The examiner can normally be reached on 9:00 a.m.-6:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Manjunath N. Rao can be reached on (571) 272-0939. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

RMD
10/3/07

Marianne P. Allen

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